

EPA Reg. No. 91889-2

PROCESSING REQUEST

Reg # 91889-2 Decision # 518173

Description: New Registration

Electronic Label & Letter (see PPLS): OR Non Electronic Label & Letter (Scanning required):

☒ Dated: 10/27/14 ☐ Dated: _____

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 09/22/14

☐ Other: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Mengyon Adams

Division: BPPD

Phone: 703-347-8496 Date: 10/27/14



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

91889-2

Date of Issuance:

10/27/2016

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Entomol 7% Lotion

Name and Address of Registrant (include ZIP Code):

Entomol LLC
P.O. Box 4097
Greenville, DE 19807

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration or registration review of your product when the EPA requires all registrants of similar products to submit such data.
2. Submit storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) data as these data requirements are not satisfied. A one-year study is required to satisfy these data requirements. You have 18 months from the date of this registration to provide these data to the EPA.

Signature of Approving Official:

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs

Date:

10/27/2016

3. Make the following labeling change before you release this product for shipment:

- Revise the EPA Registration Number to read, "EPA Reg. No. 91889-2."

4. Submit one (1) copy of the final printed labeling for the record before you release this product for shipment.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

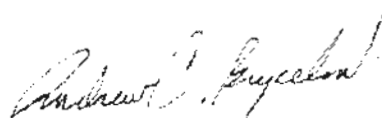
Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6. A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

- Basic CSF dated 09/22/2016.

Any CSFs other than those listed above are superseded.

If you have any questions, please contact Ms. Menyon Adams of my team by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,



Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

() – Denotes optional label language
{ } – Denotes a comment for the reviewer

Refined Oil of *Nepeta cataria* (Entomol 7% Lotion)

(Insect Repellent)(Lotion)

(Skin-applied Lotion to Repel insects)

(ABNs:)

ACTIVE INGREDIENT:

Refined Oil of *Nepeta cataria*..... 7.0%

OTHER INGREDIENTS: 93.0%

TOTAL: 100.0%

ACCEPTED

10/27/2016

Under the Federal Insecticide, Fungicide,
and Rodenticide Act as amended, the this
pesticide registered under
EPA Reg. No. 91889-2

KEEP OUT OF REACH OF CHILDREN

CAUTION

See (Back) (or) (Side) (Label Panel(s)) (Product Leaflet) for Additional
Precautionary Statements

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for further treatment advice.
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything to an unconscious person.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the poison control center at 1-800-222-1222. For non-emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: www.npic.orst.edu)	

EPA Reg. No. 91889-R
EPA Est. No. XXXXX-YY-ZZZ

NET CONTENTS:
BATCH NO.:

Manufactured By:
Entomol Products, LLC
540 Roosevelt Way
San Francisco, CA 94114

Label Version: 10/25/2016

Page 1 of 5

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS. CAUTION. Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling. If a reaction to this product is suspected, discontinue use and take off contaminated clothing. Discontinue use and consult a doctor if irritation or rash occurs.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Repellency – Repels mosquitoes and blackflies for up to 7 hours.

Apply liberally and evenly over dry, exposed skin. Do not apply over cuts, wounds or freshly shaved skin. When applying to children, dispense into an adult's hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

To apply to face: apply to palm of hand and rub on skin. Do not apply to children's hands.

For continued protection: Reapplication after six hours may be necessary.

After returning indoors, wash treated skin with soap and water or bathe. Also wash clothing before wearing it again.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Store away from children.

Pesticide Disposal and Container Handling:

Nonrefillable container. Do not reuse or refill this container.

If empty: Place in trash or offer for recycling, if available.

If partly filled: Call your local solid waste agency for disposal instructions.

Never place unused product down any indoor or outdoor drain.

- () – Denotes optional label language
{ } – Denotes a comment for the reviewer

{NOTE TO REVIEWER: All claims in this section are optional}

- Mosquito repellent
- Blackfly repellent
- Repels mosquitoes
- Repels blackflies
- Effective protection from mosquitoes and blackflies
- Effectively repels mosquitoes and black flies
- (Effective) protection (from a range of mosquitoes and blackflies)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis)
- Works great on blackflies
- Protection (from bites) from blackflies (for the whole family).
- Protection for people on the go
- Protection that fits your lifestyle
- Protects from mosquitoes (and) (blackflies) (for up to 7 hours)
- Apply every 6 hours (or as needed)
- Repels mosquitoes and blackflies for up to 7 hours
- (Smart) Outdoor protection (from annoying (mosquitoes) (and) (black flies) (for up to 7 hours)
- Repels flies (too!)
- Keeps mosquitoes and blackflies off (your family)
- Guards the whole family
- Protection that fits your (active) lifestyle
- Protect(s) your family at dusk and dawn
- An effective insect repellent
- Protection during outdoor activities
- (Sport) (Active) (Outdoor) formula
- Outdoor mosquito and blackfly protection for play and on the go
- For yard work and camping
- Protects during work, play or recreation
- Contains (a) plant-based repellent
- Plant based repellent repels (mosquitoes) (and) (blackflies) (for) (up to 7 hours)
- Contains plant extracts
- Contains the insect repellent found in (catmint) (catnip) (oil)
- (Plant based) (insect repellent without tradeoffs)
- Always carry (product name)
- For playing and relaxing outdoors
- Not oily, greasy or sticky
- No added fragrance
- Contains no dyes (or added fragrances)
- No chemical odor
- No synthetic odor
- No unpleasant odor
- Leaves pleasant feeling on skin

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- Won't stain
 - (Readily) (Easily) washed off
 - Won't harm plastics
 - Specially formulated to (feel) (and) (smell) better on your skin
 - (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula
 - No residue on skin
 - (It's) Pleasant smelling
 - Feel's comfortable to touch
 - DEET free
 - Non-DEET
 - Non-synthetic
 - Readily washed off
 - New!
-
- Repels (mosquitoes) (and) (blackflies)
 - Repels mosquitoes that may carry (West Nile) (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Cache Valley) encephalitis (for up to 7 hours)
 - Provides protection from mosquitoes
 - Up to 7 hour insect repellant
 - Up to 7 hour protection
 - Up to 7 hours of (effective) mosquito protection
 - Up to 7 hours of protection from mosquitoes. Also (protects against) (works on) (repels) (blackflies)
 - Protects for up to 7 hours against (mosquitoes) (and) (blackflies)
 - (Protects against) (Fights off) (Repels) (Works on) (mosquitoes) (and) (blackflies)
 - Protects against mosquitoes (and) (blackflies)
 - Long-lasting protection against (mosquitoes) (and) (blackflies)
 - Effective protection from mosquitoes
 - Effective protection from blackflies
 - Stay protected for up to 7 hours (from) (mosquitoes) (and)(blackflies)
 - Stay protected for up to 7 hours from mosquitoes that may carry (West Nile Virus) (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Cache Valley) encephalitis
 - Proven protection from mosquitoes
 - Mosquito protection (for up to 7 hours)
 - Biting (mosquito)(and)(blackfly) protection that you can feel confident will last up to 7 hours
 - Repels mosquitoes (for up to 7 hours)
 - Repels blackflies (for up to 7 hours)
 - Easy to (Use) (Apply)
 - For (hiking) (fishing) (hunting) (camping) (backpacking)
 - Relax and enjoy the (outdoors)(,) (the great outdoors)(,) (backyard)(,) (outside)(,) (park)(,) (woods/forest) with (up to 7 hours of) protection against (mosquitoes) (and) (blackflies)

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- Portable repellent protection
- Comfortable feel with no chemical (odor)(smell)
- Comfortable feel with pleasant smell
- Long-lasting
- Contains Refined Oil of *Nepeta cataria*

New Marketing statements:

- Essential oil based repellent, not a synthetic chemical.
- Plant based essential oil insect repellent.
- Essential oil insect repellent with up to 7 hours of effective protection [against] [mosquitoes] [and] [blackflies]
- Insect repellent with up to 7 hours of effective protection (against mosquitoes) (and) (blackflies)
- An essential oil repellent that protects against mosquitoes that may carry West Nile Virus.
- Repels mosquitoes that may carry West Nile Virus and Encephalitis
- Effective mosquito repellent
- Repels mosquitoes for up to 7 hours, which may carry West Nile Virus and Encephalitis
- Plant based, essential oil that repels mosquitoes for up to 7 hours
- A plant based insect repellent with up to 7 hours of effective protection
- Good for people
- Protects people
- Produced from a renewable resource



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: Oct. 11, 2016.

SUBJECT: Science review in support of registration of Entomol 7 % Lotion formulation, containing 7 % w/w Refined Oil of *Nepeta cataria* as its active ingredient.

Decision Number: 518173
DP Number: 434662
EPA File Symbol Number: 91889-E
Chemical Class: Biochemical
PC Code: 004801
CAS Number: 8023-84-5
Active Ingredient Tolerance Exemptions: Non- food
MRID Numbers: Cite All

FROM: Clara Fuentes, Ph. D. Entomologist
 Biochemical Pesticides Branch
 Biopesticides & Pollution Prevention Division (7511P)

A handwritten signature in black ink, appearing to be "Clara Fuentes", written over a horizontal line.

THROUGH: Angela Gonzales, Biologist
 Biochemical Pesticides Branch
 Biopesticides & Pollution Prevention Division (7511P)

A handwritten signature in black ink, appearing to be "Angela Gonzales", written over a horizontal line.

TO: Menyon Adams, Regulatory Action Leader
 Biochemical Pesticides Branch
 Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

Entomol Products LLC is requesting registration of Entomol 7 % Lotion formulation, EPA Reg. No. 91889-E, containing 7 % w/w of refined oil of *Nepeta cataria*. In support of registration, the registrant is requesting to satisfy all data requirements by bridging to data generated on substantially similar product, EPA Reg. No. 352-902, containing the same concentration, 7 % w/w, of the same active ingredient, refined oil of *Nepeta cataria*.

COMMENTS AND RECOMMENDATIONS

It is acceptable to bridge to product specific chemistry data generated on 7 % a.i. Lotion formulation, EPA Reg. No. 352-902, for registration of Entomol 7 % Lotion, EPA Reg. No. 91889-E, because both, the proposed and referenced products are substantially similar in composition.

Product Chemistry: Acceptable.

The registrant has adequately addressed product chemistry data requirement to support registration of Entomol 7 % Lotion by bridging to the following studies supporting registration of substantially similar product, 7 % Lotion, EPA Reg. No. 352-902:

- Physical/ Chemical Characteristics for 7% Lotion EPA Reg. No. 352-902 in MRID 470139-01;
- Physical/ Chemical Characteristics for 7% Lotion and 15% Lotion (EPA Reg. No. 352-902 and 352-903, respectively) in MRID 469773-10;
- Certified limits for 7 % and 15 % Lotion formulations (EPA Reg. No. 352-902 and 352-903, respectively) in MRID 470033-03, and
- Product Identity and Composition for 7 % and 15 % Lotion formulations (EPA Reg. No. 352-902 and 352-903, respectively) in MRIDs 470033-01 and 474229-01 has been now upgraded in MRID 500324-01 to reflect change in formulation.

The registrant of EPA Reg. 352-902, DuPont Crop Protection, has now amended its formulation consistently with that of substantially similar product, Entomol 7% Lotion (CSF signed and dated Sept. 22, 2016). In addition, the registrant submitted updated product chemistry data in MRID 500324-01, which includes product identity and composition, manufacturing process, and discussion of formation of impurities for 15 % and 7 % Lotion formulations, EPA Reg. No. 352-902 and 352-903, respectively. Refer to Confidential Appendix for specifications.

Mammalian toxicity: Acceptable.

The formulation amendment is not expected to change the toxicological profile of the formulations. Therefore, since the proposed and referenced lotion formulations are substantially similar, it is acceptable to bridge to toxicity data generated on 15 % Lotion formulation (EPA Reg. No. 352-903) that is being cited in support of registration of 7 % Lotion formulation (EPA Reg. No. 352-902). These data were reviewed and found acceptable per Roger Gardner's review memo dated Oct. 10, 2007.

Table 1. Toxicological profile of 15 % Lotion formulation (EPA Reg. No. 352-903).

Study Type/OCSP Guideline	LD ₅₀ /LC ₅₀ /Results	Toxicity Category	MRID
Acute Oral Toxicity/OCSP 870.1100	> 5,000 mg/kg	IV	469773-01
Acute Dermal Toxicity/OPPTS 870.1200	> 5,000 mg/kg	IV	469773-02
Acute Inhalation Toxicity/OCSP 870.1300	Waiver	IV	469773-06
Acute Eye Irritation/OCSP 870.2400	Minimal irritant	IV	469773-03
Acute Dermal Irritation/OCSP 870.2500	Non- irritating	IV	469773-04
Skin Sensitization/OCSP 870.2600	Not skin sensitizer	IV	469773-05
Hypersensitivity incidents (non-guideline)	None reported		

The cited toxicity data was reviewed by Roger Gardner's review memo dated Oct. 10, 2007.

Product Performance: Acceptable.

The formulation amendment is not expected to affect the efficacy of the products. Therefore, data from efficacy studies in MRIDs 469774-24; 469774-25; 473626-03; 470156-02 shows that complete protection times against mosquitoes averaged >6 hours 43 minutes for 7% Lotion formulation. Mean complete protection times against blackflies averaged >6 hours 59 minutes for 7% Lotion formulation. Doses applied to subjects for testing efficacy are presented on Table 2. The descriptive statistics associated to protection times are presented in Table 3.

Table 2. Doses (mg/cm²) Applied to Test Subjects.

Units	7 % Lotion
mg/cm ²	2.56
g / 600 cm ²	1.536
mg/m ²	1,792
OPPTS 810.3700 rec. values (g / 600 cm ²)	1.50

Doses for testing (2.56 mg/cm²) correspond to 1,792 mg/m² of active ingredient in 7 % lotion formulation.

Table 3. Protection times (in minutes) for 7% Lotion formulation on 2 different target pests, mosquitoes and black flies, tested in the field.

Descriptive Statistics	FL-mosquito	ME-mosquito	ME-black fly	ME-black fly
N	5	5	5	5
Minimum	270	410	338	139
25%ile	276	413	344	310
Median	282	480	480	480
75%ile	469	480	480	480
Maximum	480	480	480	480
Mean	354	453	425	412
StdDev	105	37	75	152
Std Error	47	17	33	68
Lower 95% CI	224	407	332	222
Upper 95% CI	485	499	518	601
Normality P value	>0.10	>0.10	>0.10	>0.10
Passed normality test? (α=0.05)	yes	yes	yes	yes
Skewness	0.30	-0.30	-0.30	-1.1
Kurtosis	-2.2	-2.2	-2.2	-0.92

Mosquito species encountered in Maine and Florida testing sites were identified as: *Culex* complex of spp. *Ochlerotatus intrudens*; *Psorophora ferox*, *Ochlerotatus atlanticus/tormentor*, *Ochlerotatus taeniorhynchus*, and *Culiseta melanura*; *Culex isolambdis*.

Non-target data:

Risk of exposure to non-target organisms is not expected from the use of these products as insect repellents.

References:

Roger Gardner's review memos of Mammalian toxicity and Human Health Risk Assessment data in MRIDs 469773-01 through 469773-5, dated Oct. 10, 2007.

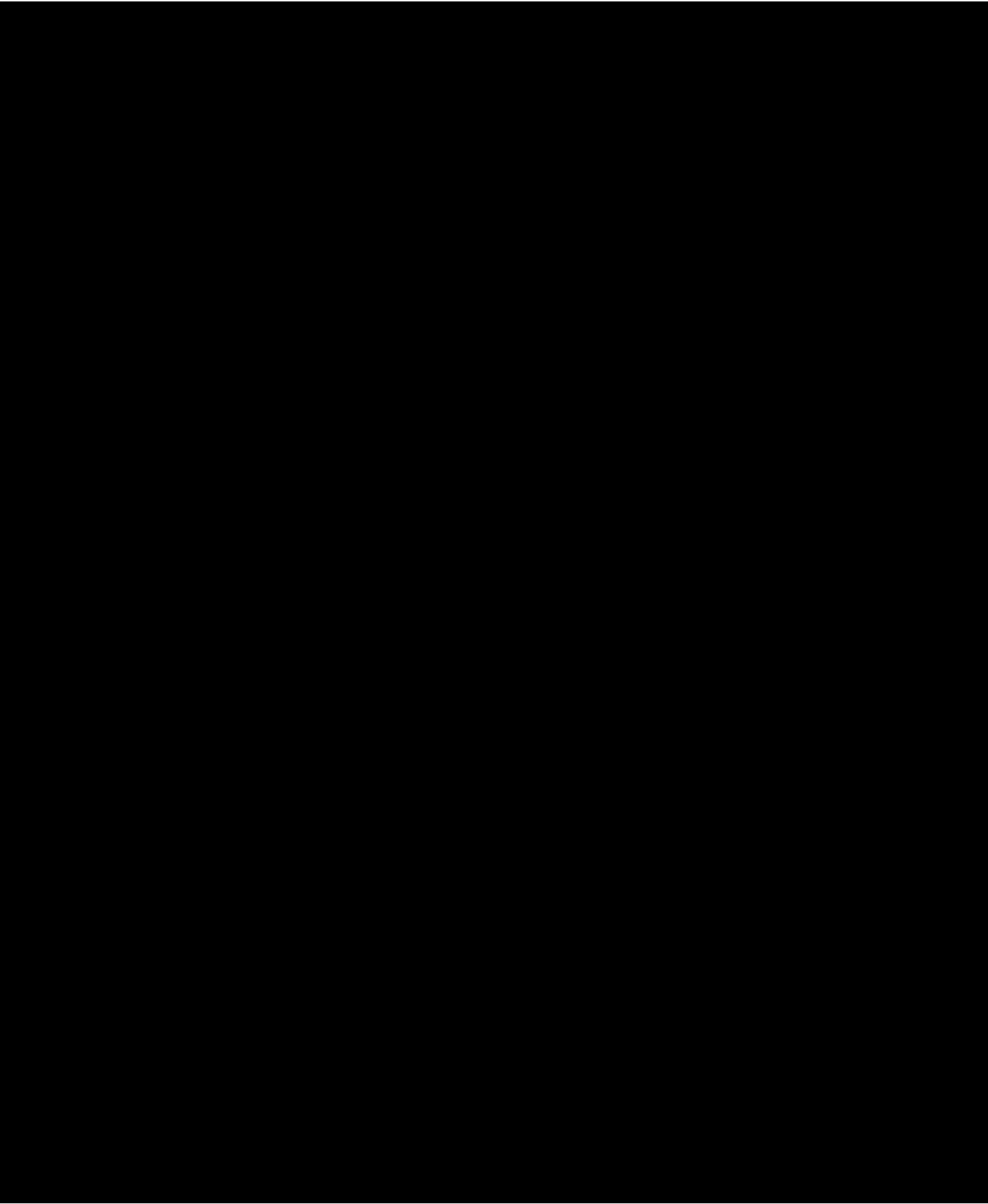
CONFIDENTIAL APPENDIX

Inert ingredient information may be entitled to confidential treatment

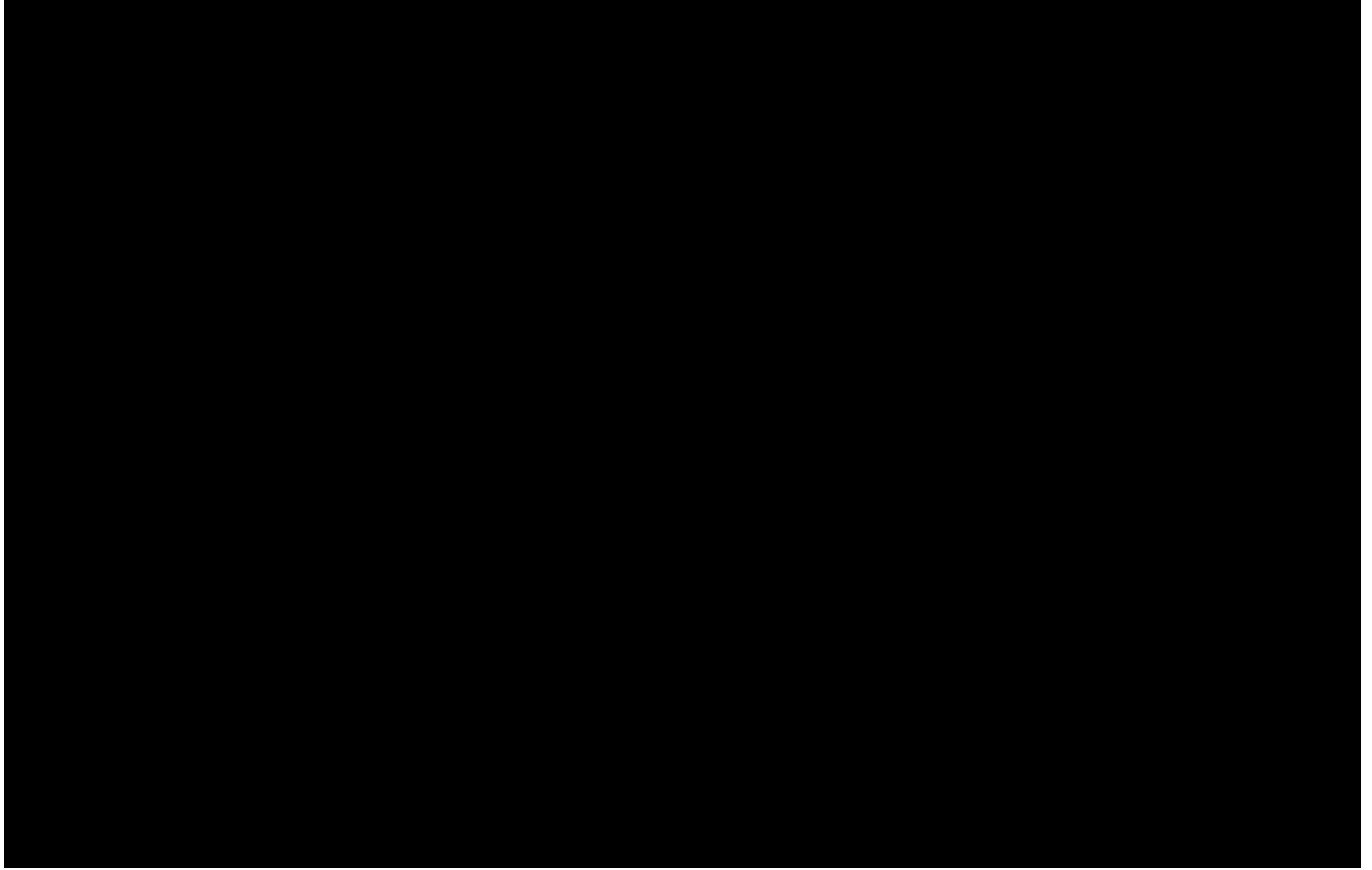
Manufacturing process information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment



CONFIDENTIAL APPENDIX



Inert ingredient information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment



Receipt

Your payment is complete

Pay.gov Tracking ID: 25RSRMNC

Agency Tracking ID: 75024442644

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card

Payment Amount: \$319.50

Transaction Date: 05/28/2016 10:55:14 PM EDT

Payment Date: 05/28/2016

Registration Number:

Company Name: Entomol Products, LLC

Company Number: 91889

Action Code: B660

Account Information

Cardholder Name: Vickie A Forster

Card Type: American Express

Card Number: *****3002

Email Confirmation Receipt

Confirmation Receipts have been emailed to:

forsterconsults@gmail.com



VOLUME TITLE:
ADMINISTRATIVE MATERIALS FOR ENTOMOL 7% LOTION

CONTENTS

**EPA Form 8570-1
Application for Pesticide Registration (Me-too)**

**EPA Form 8570-4
Confidential Statement of Formula (CSF)**

**EPA Form 8570-27
Formulator's Exemption**

**EPA Form 8570-34
Certification with Respect to Data Citation
Letter of Authorization to Cite Data**

**EPA Form 8570-35
Data Matrix**

Draft Product Labeling

PRIA Small Business Waiver Certification

PRIA Fee (Code B660) Pre-payment Receipt

**ENTOMOL PRODUCTS, LLC
540 ROOSEVELT WAY
SAN FRANCISCO, CA 94114**

EPA REGISTRATION NO.: 91889-NEW

JUNE 6, 2016

VOLUME 1 OF 1





United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

Company/Product Number 91889/NEW	2. EPA Product Manager Menyon Adams	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Entomol Products, LLC/ ENTOMOL 7% Lotion	PM# BPPD	
5. Name and Address of Applicant (Include ZIP Code) Entomol Products, LLC 540 Roosevelt Way San Francisco, CA 94114 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. 352-902 Product Name Refined Oil of <i>Nepeta cataria</i> 7% Lotion	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of a Section 3 Me-Too Registration Application

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2, 3 and 6 oz.; bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Vickie Forster		Title Agent for Entomol Products, LLC		Telephone No. (Include Area Code) 302-383-3313	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Vickie Forster</i>		3. Title Agent for Entomol Products, LLC			
4. Typed Name Vickie Forster		5. Date 6 June 2016			



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

Entomol Products, LLC
540 Roosevelt Way
San Francisco, CA 94114

EPA File Symbol/Registration Number

91889-NEW

Product Name

Entomol 7% Lotion

Date of Confidential Statement of Formula (EPA Form 8570-4)

6 June 2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Refined Oil of *Nepeta cataria*

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

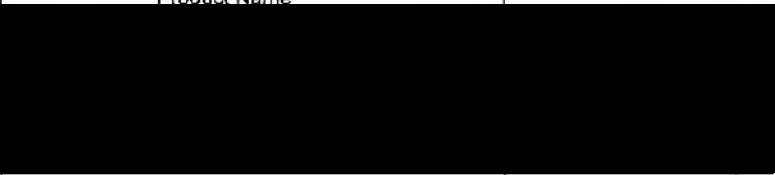
☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☒ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Refined Oil of <i>Nepeta cataria</i>		
Signature <i>Vickie Forster</i>	Name and Title Vickie Forster, Agent for Entomol Products, LLC	Date 6 June 2016



United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 91889/NEW	2. EPA Product Manager Menyon Adams	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Entomol Products, LLC/ENTOMOL 7% Lotion	PM# BPPD	
5. Name and Address of Applicant (Include ZIP Code) Entomol Products, LLC 540 Roosevelt Way San Francisco, CA 94114 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 352-902 Product Name Refined Oil of <i>Nepeta cataria</i> 7% Lotion	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of a Section 3 Me-Too Registration Application

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2, 3 and 6 oz.; bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Vickie Forster	Title Agent for Entomol Products, LLC	Telephone No. (Include Area Code) 302-383-3313
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Vickie Forster</i>	3. Title Agent for Entomol Products, LLC	
4. Typed Name Vickie Forster	5. Date 6 June 2016	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number ENTOMOL Products, LLC, 540 Roosevelt Way, San Francisco, CA 94114; 415-310-2553	EPA Registration Number/File Symbol 91889-NEW
Active Ingredient(s) and/or representative test compound(s) Refined Oil of Nepeta Cataria	Date 6 June 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Outdoor Use	Product Name ENTOMOL 7% Liquid

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

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Signature

Vickie Forster

Date

6 June 2016

Typed or Printed Name and Title

Vickie A. Forster, Agent for Entomol Products, LLC



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Active Ingredient(s) and/or representative test compound(s) Refined Oil of Nepeta Cataria	Date 23 August 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Outdoor Use	Product Name ENTOMOL 7%Lotion

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Signature <i>Vickie Forster</i>	Date 23 Aug. 2016	Typed or Printed Name and Title Vickie A. Forster, Agent for Entomol Products, LLC
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Signature

Vickie Forster

Date

23 Aug. 2016

Typed or Printed Name and Title

Vickie A. Forster, Agent for Entomol Products, LLC



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Signature <i>Vickie Forster</i>	Date 23 Aug. 2016	Typed or Printed Name and Title Vickie A. Forster, Agent for Entomol Products, LLC
------------------------------------	----------------------	---



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

Entomol Products, LLC
540 Roosevelt Way
San Francisco, CA 94114

EPA File Symbol/Registration Number

91889-NEW

Product Name

Entomol 7% Lotion

Date of Confidential Statement of Formula (EPA Form 8570-4)

6 June 2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Refined Oil of *Nepeta cataria*

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☒ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Refined Oil of <i>Nepeta cataria</i>	[REDACTED]	[REDACTED]
Signature <i>Vickie Forster</i>	Name and Title Vickie Forster, Agent for Entomol Products, LLC	Date 6 June 2016



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Signature <i>Vickie Forster</i>	Date 6 June 2016	Typed or Printed Name and Title Vickie A. Forster, Agent for Entomol Products, LLC
------------------------------------	---------------------	---

S: 990978

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Application Type: Pending Product Amendment

Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

Company: 91889 ENTOMOL LLC.

V

Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 91889-E

Product Name: ENTOMOL 7% LOTION

Override#:

Me Too

☒ Section 3: 352-902

Me Too Product

Name: REFINED OIL OF NEPETA CATARIA 7% LOTIC ...

Application Date: 23-Aug-2016



OPP Rec'd Date: 24-Aug-2016



Front End Date: 24-Aug-2016



Risk Manager Send Date: 31-Aug-2016



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

RESUBMISSION AMENDMENT FOR PENDING PRODUCT

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Des

CSF

III

View/Edit



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 31, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

VICKIE FORSTER
ENTOMOL LLC.
PO Box 4097
GREENVILLE, DE 19807-

PRODUCT NAME: ENTOMOL 7% LOTION
COMPANY NAME: ENTOMOL LLC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 91889-E
EPA RECEIPT DATE: 08/24/16

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 305-6928.

Sincerely,

A handwritten signature in black ink, appearing to be "S. [unclear]", written over the word "Sincerely,".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



Andrew Bryceland, Team Lead
Office of Pesticide Programs (7504P)
Biochemicals Registration Branch
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Dear Mr. Bryceland:

ENTOMOL Products, LLC (Entomol, 540 Roosevelt Way, San Francisco, CA 94114; EPA Company No. 91889) is submitting additional data in response to EPA's 10-day deficiency letter dated August 10, 2016 to support the application for pesticide registration for **Entomol 7% Lotion**. Please find enclosed the following documentation in support of this continued application for registration:

- Application for Pesticide Registration (EPA Form 8570-1);
- Revised Basic CSF dated August 23, 2016 (EPA Form 8570-4);
- Formulator's Exemption form (EPA Form 8570-27); and
- Copy of EPA's 10-Day Deficiency Letter D-518173 (for Agency's reference).

Briefly, the Agency determined that the emulsifier listed on the CSF dated June 6, 2016 was not found in the Agency's inert database as being cleared for pesticidal use. Therefore the emulsifier is being replaced in the formulation with three EPA approved inert ingredients that are a direct replacement that will perform the same function of the original emulsifier. Note that the three components are already listed on the Agency's inert ingredient database. Further details are provided in the confidential enclosure to this letter.

An updated CSF and an updated Formulator's Exemption form are enclosed with this letter and support the registration application for **Entomol 7% Lotion**.

ENTOMOL

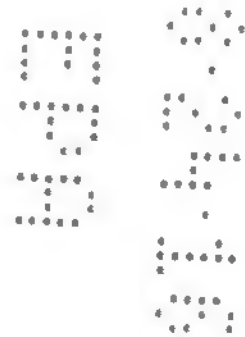
GOOD FOR PEOPLE. BAD FOR BUGS.

If you have any questions, please contact me at (302) 383-3313 (phone), or forsterconsults@gmail.com (email).

Sincerely,

Vickie Forster

Vickie Forster
Agent for Entomol Products, LLC



ENTOMOL

GOOD FOR PEOPLE. BAD FOR BUGS.

Confidential Enclosure





United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 91889-E	2. EPA Product Manager Andrew Bryceland	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Entomol Products, LLC/ ENTOMOL 7% Lotion	PM# BPPD	
5. Name and Address of Applicant (Include ZIP Code) Entomol Products, LLC 540 Roosevelt Way San Francisco, CA 94114 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 352-902 Product Name Refined Oil of <i>Nepeta cataria</i> 7% Lotion	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to: Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of revised CSF for Section 3 Me-Too Registration Application

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2, 3 and 6 oz.; bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Vickie Forster	Title Agent for Entomol Products, LLC	Telephone No. (Include Area Code) 302-383-3313
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Vickie Forster</i>	3. Title Agent for Entomol Products, LLC	
4. Typed Name Vickie Forster	5. Date 23 August 2016	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to **Director, Collection Strategies Division (2822T) U.S. Environmental Protection Agency, 1200 Pennsylvania Ave, NW, Washington, DC 20460.**

INSTRUCTIONS: This form is to be used all applications for new registration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-34), [If not exempted by 40 CFR 152.81(b)(4)]
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Data Matrix.

Submission of Labeling -Labeling should first be submitted in the form of draft labeling with all applications. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data -Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with new registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amendments actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - The section must be completed, as applicable, for all registration actions.

1. **Company /Product Number** - Insert your company number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** -If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** -Specify the proposed classification of this product. For most products the classification would be "None".
4. **Product Name** -Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** -The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting on behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** -FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II -This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. **The Explanation Section should be used for any additional information regarding Sections I and II.**

1. **Subject of submission** -Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)", "amend the Confidential Statement of Formula by...", "reregistration submission", "general label revision of direction for use", "notification for...". Attach a separate page if additional space is needed.

SECTION III - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** -Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** -Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** -Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** -Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** -Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) -This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5 Self-explanatory
6. EPA Use Only



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

Entomol Products, LLC
540 Roosevelt Way
San Francisco, CA 94114

EPA File Symbol/Registration Number

91889-E

Product Name

Entomol 7% Lotion

Date of Confidential Statement of Formula (EPA Form 8570-4)

23 August 2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Refined Oil of *Nepeta cataria*

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☒ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Refined Oil of <i>Nepeta cataria</i>		
Signature <i>Vickie Forster</i>	Name and Title Vickie Forster, Agent for Entomol Products, LLC	Date 23 August 2016



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 10, 2016

BY EMAIL

OPP Decision Number: 518173
EPA File Symbol: 91889-E
Product Name: Entomol 7% Lotion
EPA Receipt Date: June 06, 2016
EPA Company Number: 91889
Company Name: Entomol, LLC

Vickie Foster, Agent
Agent for Entomol Products, LLC
c/o Foster & Associates Consulting, LLC
PO Box 4097
GREENVILLE, DE 19807

Dear Ms. Foster:

The U.S. Environmental Protection Agency (Agency or EPA) has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). The EPA has determined that your application has not passed the preliminary technical screening and therefore is subject to rejection if the application is not corrected.

Specifically, you must provide the data and/or information described below:

Your inert ingredient, the emulsifier that's listed on line six on the basic Confidential Statement of Formula (CSF) dated June 06, 2016, was not found in the Agency's inert database as being cleared for pesticidal use. All inerts and/or other ingredients must be permitted for pesticidal use in one of the three categories (Food and Nonfood use, Nonfood use only or Fragrances) or under Minimal Risk FIFRA Section 25(b) Inert Ingredient. Your emulsifier is not. Given that, your application has been deemed deficient. You must either: 1). Replace the ingredient with an ingredient that is cleared for pesticidal use and submit a new application that references the similar product or 2). Initiate the clearance process by contacting the inert ingredient assessment branch (IIAB) via email at inertsbranch@epa.gov or you can visit the inert ingredient website at <https://www.epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance> for further guidance.

Moreover, your proposed end use product has a PRIA Action Code of B660, substantially similar in formulation to DuPont's Refined Oil of Nepeta Cataria 7% Lotion (EPA Reg. No. 352-902). Subsequently, DuPont has acknowledge our and their error; therefore, DuPont will amend their basic formulation as well.

In order for the review of your pesticide product to continue, you will need to correct your application to address the item listed above within 10 business days of the date you received this letter. The EPA must receive your correction by the 10th business day. The EPA recommends sending your correction by email to the contact listed below to ensure it is received in a timely manner. If studies or confidential business information are being submitted by mail, a complete courtesy copy, minus confidential information, received by email by the deadline will be considered timely. If you cannot correct the application or do not respond within 10 business days, your application will be rejected. At this time, you could also choose to withdraw your application.

If you have questions concerning this letter, please contact Menyon Adams of my branch by telephone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

A handwritten signature in cursive script, appearing to read "Andrew Bryceland".

Andrew Bryceland
Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

VOLUME TITLE:

ADMINISTRATIVE MATERIALS FOR ENTOMOL 7% LOTION

CONTENTS

**EPA Form 8570-1
Application for Pesticide Registration (Me-too)**

**EPA Form 8570-4
Confidential Statement of Formula (CSF)**

**EPA Form 8570-27
Formulator's Exemption**

**EPA Form 8570-34
Certification with Respect to Data Citation
Letter of Authorization to Cite Data**

**EPA Form 8570-35
Data Matrix**

Draft Product Labeling

PRIA Small Business Waiver Certification

PRIA Fee (Code B660) Pre-payment Receipt

**ENTOMOL PRODUCTS, LLC
540 ROOSEVELT WAY
SAN FRANCISCO, CA 94114**

EPA REGISTRATION NO.: 91889-NEW

JUNE 6, 2016

VOLUME 1 OF 1



ENTOMOL

GOOD FOR PEOPLE. BAD FOR BUGS.

August 23, 2016

Andrew Bryceland, Team Lead
Office of Pesticide Programs (7504P)
Biochemicals Registration Branch
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attn: Menyon Adams, Reviewer

Subject: Response to EPA's 10 Day Deficiency Letter
Entomol 7% Lotion, EPA File Symbol 91889-E
OPP Decision No. 518173

Dear Mr. Bryceland:

ENTOMOL Products, LLC (Entomol, 540 Roosevelt Way, San Francisco, CA 94114; EPA Company No. 91889) is submitting additional data in response to EPA's 10-day deficiency letter dated August 10, 2016 to support the application for pesticide registration for Entomol 7% Lotion. Please find enclosed the following documentation in support of this continued application for registration:

- Application for Pesticide Registration (EPA Form 8570-1);
- Revised Basic CSF dated August 23, 2016 (EPA Form 8570-4);
- Formulator's Exemption form (EPA Form 8570-27); and
- Copy of EPA's 10-Day Deficiency Letter D-518173 (for Agency's reference).

Briefly, the Agency determined that the emulsifier listed on the CSF dated June 6, 2016 was not found in the Agency's inert database as being cleared for pesticidal use. Therefore the emulsifier is being replaced in the formulation with three EPA approved inert ingredients that are a direct replacement that will perform the same function of the original emulsifier. Note that the three components are already listed on the Agency's inert ingredient database. Further details are provided in the confidential enclosure to this letter.

An updated CSF and an updated Formulator's Exemption form are enclosed with this letter and support the registration application for Entomol 7% Lotion.

ENTOMOL

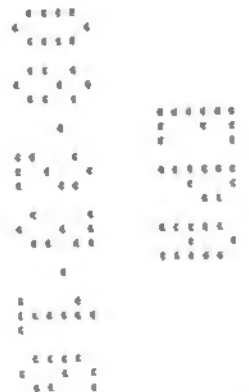
GOOD FOR PEOPLE. BAD FOR BUGS.

If you have any questions, please contact me at (302) 383-3313 (phone), or forsterconsults@gmail.com (email).

Sincerely,

Vickie Forster

Vickie Forster
Agent for Entomol Products, LLC





United States Environmental Protection Agency
401 M. Street, S.W.
Washington, DC 20460

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DATA MATRIX

Date: 6 June 2016

Applicant's/Registrant's Name & Address:
Entomol Products, LLC
540 Roosevelt Way
San Francisco, CA 94114

EPA Reg. No./File Symbol: 91889-NEW
Product: ENTOMOL 7% Lotion
CAS Registry No. 952722-18-8
OPP Chemical Code 004801

Ingredient: Refined Oil of *Nepeta cataria*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
830.1500 830.1670		CITE-ALL	352	EXC	
830.1700		CITE-ALL	352	EXC	
830.1750		CITE-ALL	352	EXC	
830.1800		CITE-ALL	352	EXC	
830.6302 to 830.7950		CITE-ALL	352	EXC	
870.1100		CITE-ALL	352	EXC	
870.1200		CITE-ALL	352	EXC	
870.1300		CITE-ALL	352	EXC	
870.2400		CITE-ALL	352	EXC	
870.2500		CITE-ALL	352	EXC	
870.2600		CITE-ALL	352	EXC	
870.3100		CITE-ALL	352	EXC	
870.3250		CITE-ALL	352	EXC	
870.5100, 870.5300, 870.5375		CITE-ALL	352	EXC	
870.3700		CITE-ALL	352	EXC	
850.2100		CITE-ALL	352	EXC	
850.2200		CITE-ALL	352	EXC	
850.2200		CITE-ALL	352	EXC	
850.1010		CITE-ALL	352	EXC	
850.1075		CITE-ALL	352	EXC	
850.4400 - 850.4800		CITE-ALL	352	EXC	
880.4350		CITE-ALL	352	EXC	

Signature: *Vickie Forster*
Name and Title: Vickie Forster, Agent for Entomol Products, LLC

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Date: 6 June 2016



United States Environmental Protection Agency
401 M. Street, S.W.
Washington, DC 20460

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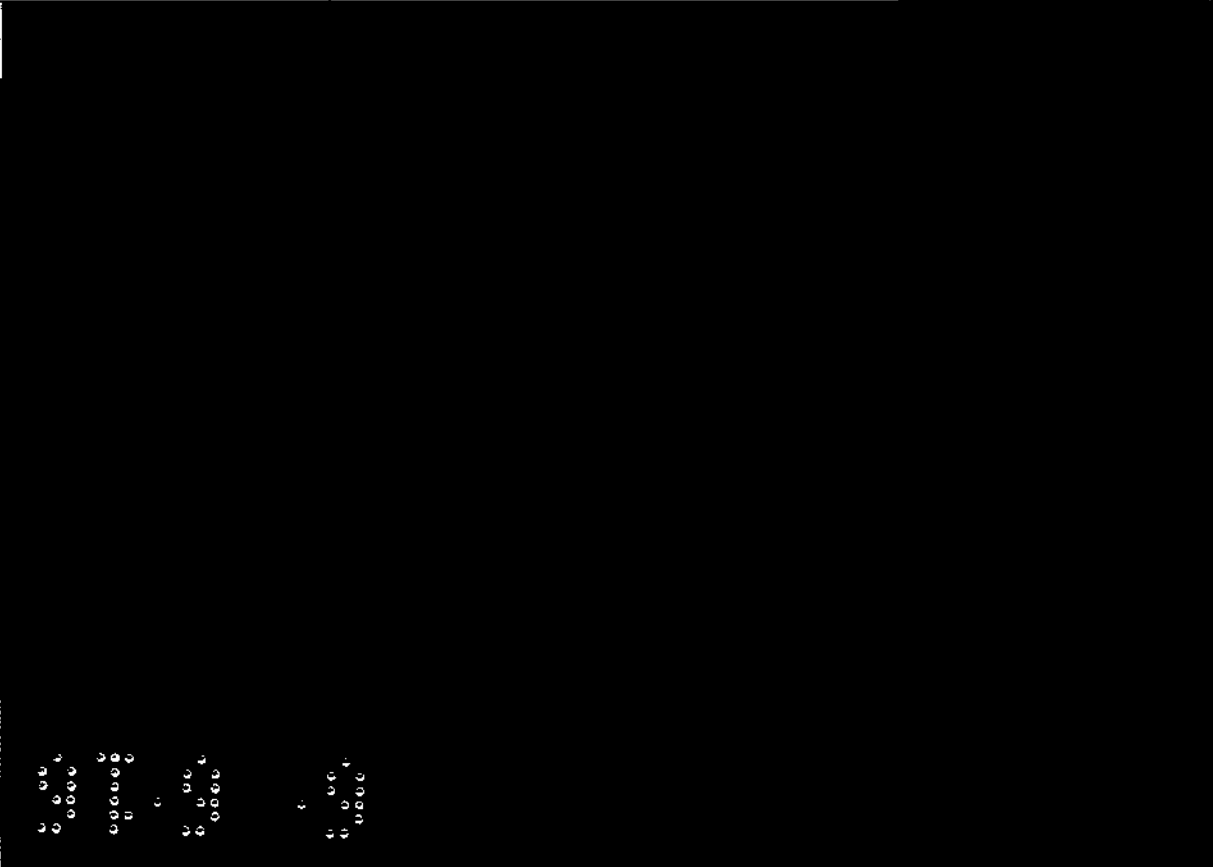
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		352		EXC	
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870.2400		CITE-ALL	352	EXC	
870.2500		CITE-ALL	352	EXC	
870.2600		CITE-ALL	352	EXC	
870.3100		CITE-ALL	352	EXC	
870.3250		CITE-ALL	352	EXC	
870.5100, 870.5300, 870.5375		CITE-ALL	352	EXC	
870.3700		CITE-ALL	352	EXC	
850.2100		CITE-ALL	352	EXC	
850.2200		CITE-ALL	352	EXC	
850.2200		CITE-ALL	352	EXC	
850.1010		CITE-ALL	352	EXC	
850.1075		CITE-ALL	352	EXC	
850.4400 - 850.4800		CITE-ALL	352	EXC	
890.4350		CITE-ALL	352	EXC	

Signature: *Vickie Forster*
Name and Title: Vickie Forster, Agent for Entomol Products, LLC

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Date: 6 June 2016



United States Environmental Protection Agency
401 M. Street, S.W.
Washington, DC 20460

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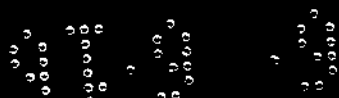
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			352	EXC	

Vickie Forster

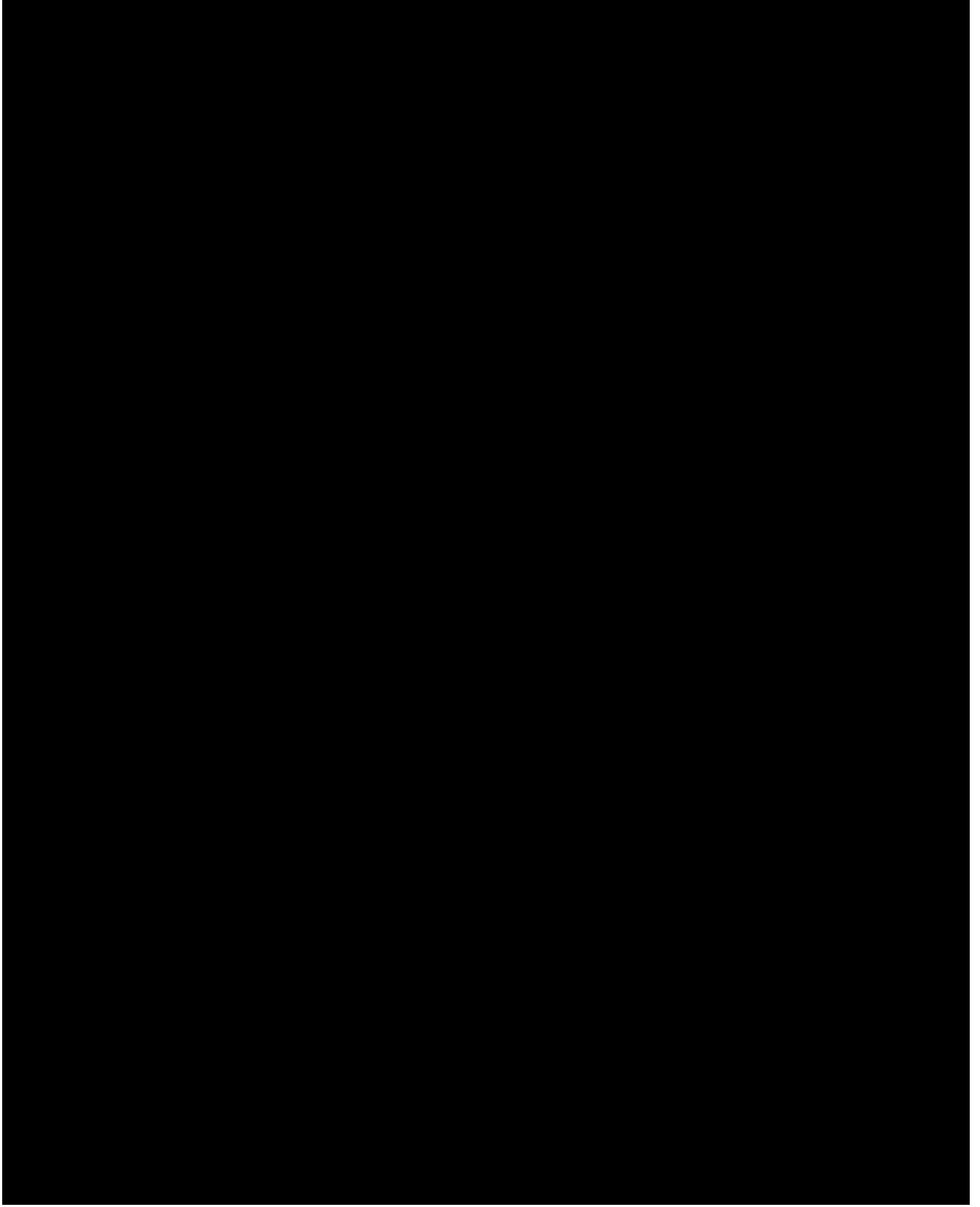
Signature:
Name and Title: Vickie Forster, Agent for Entomol Products, LLC

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Date: 6 June 2016

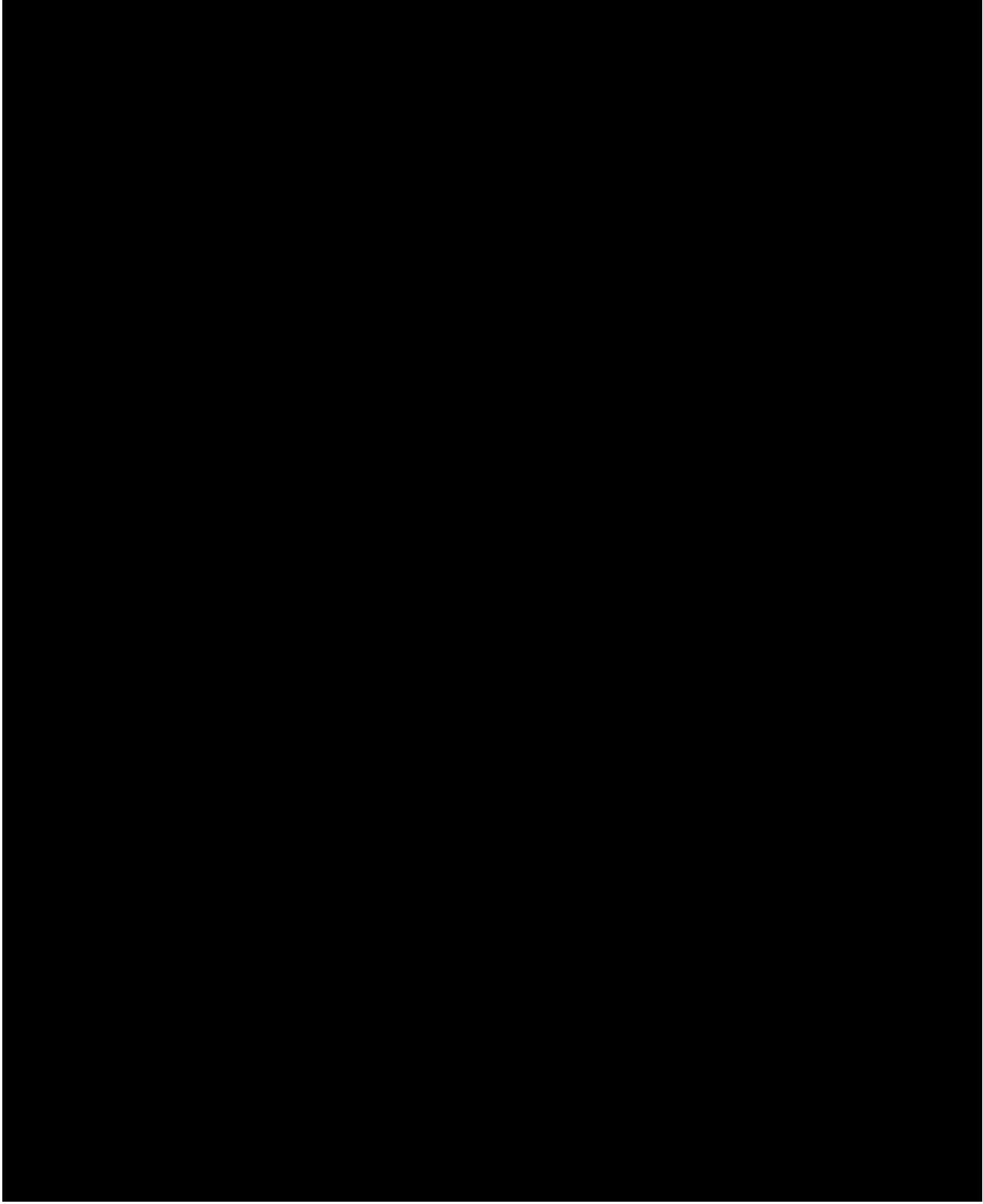
Inert ingredient information may be entitled to confidential treatment

Internal deliberative information



Inert ingredient information may be entitled to confidential treatment

Internal deliberative information



Bryceland, Andrew

From: VICKIE FORSTER <forsterconsults@gmail.com>
Sent: Friday, June 24, 2016 12:15 PM
To: Bryceland, Andrew; Hollis, Linda; Sheahin, Marc; Shah, Pv
Cc: Mark Sloneker; James Messina
Subject: EPA Reg. Nos. 91889-E and 91889-R
Attachments: Progress Update Inert Status 91889-E.doc; Completed Inert Status 91889-R.doc

Dear Mr. Bryceland, Dr. Shah and Mr. Sheahin,

As noted in my email yesterday to Mr. Bryceland, we are working closely with all of the inert ingredient suppliers to submit letters to EPA to add their products to the EPA Tradename Database. Please find attached an update on the status of submissions to EPA. All inert ingredient suppliers for 91889-R have submitted information to EPA (Dr. Shah and Mr. Sheahin). Three of the six inert ingredient suppliers for 91889-E have submitted information to EPA (Dr. Shah and Mr. Sheahin). We are hoping the other suppliers will submit later today or Monday. We will keep the Agency updated.

Please make sure to confirm the submissions and notify Mr. Bryceland as we do not want the registration applications rejected on Monday.

Additionally, the two Entomol formulations are identical to the EPA registered formulations under 352-902 and 352-904 (approved by EPA in 2009).

Please let me know if you have any questions.

Thank you and Best regards,

Vickie Forster

INERT CLEARANCE STATUS FORM

Reviewer Name: Marc Sheahin			Request Date: 6/15/2016
Tel: 703-347-8686	ISB	CUBE: S-4811	MAIL CODE: 7502P

A. COMMENTS:

Inert Issue: The inert ingredients are not found in the Agency database.

B. PESTICIDE PRODUCT INFORMATION:

Receipt Number: 987299	Date on CSF: 06/06/2016	Food-Use Pesticide: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
EPA Reg. No/File Symbol: 91889-E	Formulation: Basic	

C. INGREDIENT INFORMATION:

Ingredient No. 1	Tolerance Exemption(s) ¹					
	910	920	930	940	950	960
Chem. Name: [REDACTED]						
Trade Name: [REDACTED]						
CAS Reg. No: [REDACTED]						

Comments: The inert is not found in the Agency database.

Request letter to add to Trade Name database submitted to Agency on

Ingredient No. 2

Chem. Name: [REDACTED]						
Trade Name: [REDACTED]						
CAS Reg. No: [REDACTED]						

Comments: The inert is not found in the Agency database.

Received on 6/23/2016 a Confidential Product Composition document. Emailed

¹Language from the Code of Federal Regulations (40 CFR 180, subpart D):

40 CFR 180.910: Inert ingredients used pre- and post-harvest; 40 CFR 180.920: Inert ingredients used pre-harvest; 40 CFR 180.930: Inert ingredients applied to animals; 40 CFR 180.940: Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations; 40 CFR 180.950: Tolerance exemptions for minimal risk active and inert ingredients; and 40 CFR 180.960: Polymers.

Reviewer Name: Marc Sheahin

Review Date: 06/15/2016

Ingredient No. 3

Chem. Name								
Trade Name								
CAS Reg.								

Comments: The inert is not found in the Agency database.

regarding TN db. She confirmed that a request letter to add product to Trade Name database will be supplied to EPA.

Ingredient No. 4

Chem. Name								
Trade Name								
CAS Reg.								

Comments: The inert is not found in the Agency database.

Request letter to add to Trade Name database submitted to Agency on

Ingredient No. 5

Chem. Name								
Trade Name								
CAS Reg.								

Comments: The inert is not found in the Agency database.

Request letter to add to Trade Name database submitted to Agency on

Inert ingredient information may be entitled to confidential treatment

Ingredient No. 6

Chem. Name	[REDACTED]						
Trade Name							
CAS Reg.							
Comments: The inert is not found in the Agency database.							
Spoke to [REDACTED] regarding TN db. She confirmed that a request letter to add product to Trade Name database will be supplied to EPA.							

INERT CLEARANCE STATUS FORM

Reviewer Name: Marc Sheahin			Request Date: 6/15/2016
Tel: 703-347-8686	ISB	CUBE: S-4811	MAIL CODE: 7502P

A. COMMENTS:

Inert Issue: The inert ingredients are not found in the Agency database.

B. PESTICIDE PRODUCT INFORMATION:

Receipt Number: 987295	Date on CSF: 06/06/2016	Food-Use Pesticide: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
EPA Reg. No/File Symbol: 91889-R	Formulation: Basic	

C. INGREDIENT INFORMATION:

Ingredient No. 1	Tolerance Exemption(s) ¹					
	910	920	930	940	950	960
Chem. Name:						
Trade Name:						
CAS Reg. No						
Comments: The inert is not found in the Agency database.						
Request letter to add to Trade Name database submitted to Agency on [REDACTED]						

Ingredient No. 2						
Chem. Name:						
Trade Name:						
CAS Reg.						
Comments: The inert is not found in the Agency database.						
Request letter to add to Trade Name database submitted to Agency on [REDACTED]						

¹Language from the Code of Federal Regulations (40 CFR 180, subpart D):

40 CFR 180.910: Inert ingredients used pre- and post-harvest; 40 CFR 180.920: Inert ingredients used pre-harvest; 40 CFR 180.930: Inert ingredients applied to animals; 40 CFR 180.940: Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations; 40 CFR 180.950: Tolerance exemptions for minimal risk active and inert ingredients; and 40 CFR 180.960: Polymers.

Reviewer Name: Marc Sheahin

Review Date: 06/15/2016

Ingredient No. 3

Chem. Name:							
Trade Name:							
CAS Reg.							
Comments: The inert is not found in the Agency database.							
Request letter to add to Trade Name database submitted to Agency on							

Ingredient No. 4

Chem. Name:							
Trade Name:							
CAS Reg.							
Comments: The inert is not found in the Agency database.							
Request letter to add to Trade Name database submitted to Agency on							

If your application requires the review and approval of a label and is not a biopesticide, your Pre-decisional Determination Due Date will be either:

two weeks before the PRIA due date (for actions with a decision review time frame \leq 12 months), or

four weeks before the PRIA due date (for actions with a decision review time frame $>$ 12 months)

This is an automated email; please do not try to respond to it.

EPA Letter Oct. 16, 2007 page/comment

"Refined Oil of *Nepeta cataria*" 15% Lotion; EPA File Symbol 71654-ER

"Refined Oil of *Nepeta cataria*" 7% Lotion; EPA File Symbol 71654-EG

Page 2/a.	
Page 2/b.	
Page 3/c.	
Page 3/d.	
Page 3/e.	
Page 3/f.	CSF dated April 23, 2008 is correct. Refer to attached Volume 2 for revised guideline study 880.1100 and 880.1200 (supersede 47003301)
Page 3/g.	CSF and Volume 2 revised guideline study 880.1100 and 880.1200 (supersede 47003301)
Page 3/h.	CSF blocks #5 and #6 completed
Page 3/IIa.	One-Year Storage Stability study (830.6313) – Time 0 results show zero of the named component as expected. Study to be submitted at the end of the one-year cycle.
Page 3/IIb.	Refer to Volume 2; page 10 thru page 78
Page 3/IIc.	After step A2.3 (Refer to Volume 2); Each lot is visually examined for typical properties. A sample is taken for specific gravity measurement and is analyzed for active ingredient following the Enforcement Analytical Method; (MRID 470033020).
Page 3/IId.	
Page 3-4/IIf	
Page 4/III.a.	<u>Oxidation-Reduction:</u> Not Required – the formula does not contain an oxidizing-reducing agent. (Ref. 40CFR158.190; note #5) <u>Chemical Incompatibility:</u> Not Required – the formula is a ready-to-use end-use formula which does not require dilution or mixing with other chemicals. <u>Explosibility:</u> Not Required – the formula is not potentially explosive. (Ref. 40CFR158.190; note #7)
Page 4/IIIb.	One-year guideline storage stability and corrosion characteristics are in-progress.
Page 5/IV.	Efficacy study comments were addressed in the February 28, 2008 submission on the TGAI.



Receipt

Your payment is complete

Pay.gov Tracking ID: 25RSRMNC

Agency Tracking ID: 75024442644

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card

Payment Amount: \$319.50

Transaction Date: 05/28/2016 10:55:14 PM EDT

Payment Date: 05/28/2016

Registration Number:

Company Name: Entomol Products, LLC

Company Number: 91889

Action Code: B660

Account Information

Cardholder Name: Vickie A Forster

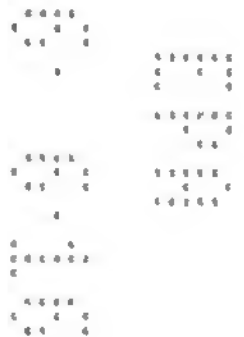
Card Type: American Express

Card Number: *****3002

Email Confirmation Receipt

Confirmation Receipts have been emailed to:

forsterconsults@gmail.com



PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 6-6-16

Experts In-Processing Signature: B.B. Date 6-9-18

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>91889-E</u>		EPA Receipt Date: <u>6-6-16</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
			X			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5					X
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Documentation: PASS

- All required forms are complete.

Inerts: FAIL

- Inerts not approved, see Inert status form.

II-3: N/A

- No study

Status: FAIL

- MS 06/21/16

- Rej. letter on (H.)

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Vickie Forster
Agent for: Entomol, LLC
Forster & Associates Consulting, LLC
PO Box 4097
Greenville, DE 19807

RE: Application for Registration dated: 08-JUN-2016
Date Fee Payment: 06-JUN-2016
Product Name: ENTOMOL 7% LOTION
EPA Registration Number: 91889-E
Decision Number: D-518173

Dear Registrant:

The Agency has completed its initial contents screen of your application pursuant to Section 33(f)(4)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended the Pesticide Registration Improvement Renewal Act. The Agency has determined that your application did not pass the initial contents screen and therefore must be rejected.

Specifically, the following items were missing or improperly formatted: Inert ingredients listed on the Confidential Statement of Formula were not found in the Agency database.

In addition, in our attempts to clarify the above issue you failed to provide corrections in a timely manner. You were contacted by an Agency contractor via e-mail on June 15, 2016, June 20, 2016 and June 21, 2016.

Furthermore, pursuant to FIFRA Section 33(b)(2)(G) the Agency must retain 25% of the registration service fee. Any future submissions to the Agency will be considered a new application and subject to the full registration service fee and another initial contents screen of all necessary fees, forms, data, and draft labeling.

Sincerely,

XXXXXXXXX, Director
Office of Pesticide Programs

Sheahin, Marc

From: VICKIE FORSTER <forsterconsults@gmail.com>
Sent: Tuesday, June 21, 2016 8:58 AM
To: Sheahin, Marc
Subject: Re: Applications for Reg.# 91889-E and R - CONFIDENTIAL

Thank you, Marc.

I appreciate your feedback.

Best regards,

Vickie

Sent from my iPhone

On Jun 21, 2016, at 8:53 AM, Sheahin, Marc <Sheahin.Marc@epa.gov> wrote:

Good morning Vickie,

Yes, I will send both applications to the PM today as is. Please send any future correspondence and supporting documents to the PM from here on out.

Best,
Marc

From: VICKIE FORSTER [<mailto:forsterconsults@gmail.com>]
Sent: Monday, June 20, 2016 4:05 PM
To: Sheahin, Marc <Sheahin.Marc@epa.gov>
Subject: Re: Applications for Reg.# 91889-E and R - CONFIDENTIAL

Hi Marc,

Regarding the inerts for these formulations that are not listed on the EPA Database:

We are actively talking with each of the suppliers to get them to submit the necessary information to EPA (directly) to add the inerts to the EPA Tradename Database. This will take some time, perhaps 1-3 weeks.

How would you like to proceed?

Will the applications be sent to the PM while waiting for this info?

Thank you and Best regards,

Vickie

Sent from my iPhone

On Jun 20, 2016, at 10:53 AM, Sheahin, Marc <Sheahin.Marc@epa.gov> wrote:

Hi Vickie,

Just a reminder that the preliminary review deadline for these two applications is tomorrow, 06/21. If the alternate formulation will not be available by about noon, please forward it to the appropriate PM instead. Thank you.

Marc

From: Vickie Forster [<mailto:forsterconsults@gmail.com>]

Sent: Wednesday, June 15, 2016 11:52 AM

To: Sheahin, Marc <Sheahin.Marc@epa.gov>

Subject: Re: Applications for Reg.# 91889-E and R - CONFIDENTIAL

Thank you, Mr. Sheahin,

Since this is a me-too product, we will contact the primary registrant and ask if there is an alternate formulation that substitutes the inerts not in the Agency database for ones that are in the database.

I appreciate your contacting me so quickly.

Best regards,

Vickie

On Jun 15, 2016, at 11:25 AM, Sheahin, Marc
<Sheahin.Marc@epa.gov> wrote:

Dear Ms. Forster,

My name is Marc Sheahin and I am a contractor with the EPA. I am contacting you in regards to your submission in support of Entomol 7% Lotion and Entomol 7% Liquid (EPA Reg. Number: 91889-E and R). We have found a deficiency with the submissions that will need to be addressed:

1. Inert ingredients listed on the confidential statement of formulas were not found in the Agency database. You may obtain a letter from the supplier or remove the inert from the CSF. Refer to the attached inert status forms for additional details.

Please send all necessary documents to this e-mail address by 06/21. If you have any questions, please do not hesitate to contact me.

Best,
Marc Sheahin

Contractor, US EPA
2777 S. Crystal Drive, S-4811
Arlington, VA 22202
(703) 347-8686
Email: sheahin.marc@epa.gov

<Inert Status 91889-E.doc><Inert Status 91889-R.doc>



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 8, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-518173
EPA File Symbol or Registration Number: 91889-E
Product Name: ENTOMOL 7% LOTION
EPA Receipt Date: 06-Jun-2016
EPA Company Number: 91889
Company Name: ENTOMOL LLC.

VICKIE FORSTER
AGENT FOR: ENTOMOL LLC.
FORSTER & ASSOCIATES CONSULTING, LLC
PO BOX 4097
GREENVILLE, DE 19807

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B660

NEW PRODUCT;MICROBIAL/BIOCHEMICAL;REGISTERED SOURCE OF ACTIVE
INGREDIENT;ME-TOO;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-1259.

Sincerely,

A handwritten signature in cursive script that reads "Teresa Downs".

Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

^W {987299m~

This package includes the following

☒ New Registration

☐ Amendment

☐ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: 75

for Division

☐ AD

☒ BPPD

☐ RD

Risk Mgr. 91

Receipt No.

S- 987299

EPA File Symbol/Reg. No.

91889-E

Pin-Punch Date:

6/6/2016

☐ This item is NOT subject to FFS action.

Action Code:

Requested: B660

Granted: B660

Amount Due: \$ 1,278

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Andrew Beyersland

Date: 6-7-16

Remarks:



Receipt for Section 3

S: 987299

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

Company: 91889 ENTOMOL LLC.



Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 91889-E Product Name: ENTOMOL 7% LOTION

Override#:

Me Too
Section3: 352-902

Me Too Product
Name: REFINED OIL OF NEPETA CATARIA 7% LOTIC

Application Date: 06-Jun-2016

OPP Rec'd Date: 06-Jun-2016

Front End Date: 06-Jun-2016

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

NEW REGISTRATION

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

CSF

Paper Label

View/Edit



Receipt

Your payment is complete

Pay.gov Tracking ID: 25RSRMNC

Agency Tracking ID: 75024442644

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card

Payment Amount: \$319.50

Transaction Date: 05/28/2016 10:55:14 PM EDT

Payment Date: 05/28/2016

Registration Number:

Company Name: Entomol Products, LLC

Company Number: 91889

Action Code: B660

Account Information

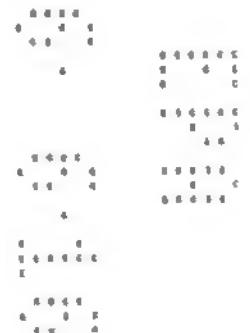
Cardholder Name: Vickie A Forster

Card Type: American Express

Card Number: *****3002

Email Confirmation Receipt

Confirmation Receipts have been emailed to:
orsterconsults@gmail.com





United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 91889/NEW	2. EPA Product Manager Menyon Adams	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Entomol Products, LLC/ ENTOMOL 7% Lotion	PM# BPPD	
5. Name and Address of Applicant (Include ZIP Code) Entomol Products, LLC 540 Roosevelt Way San Francisco, CA 94114 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 352-902 Product Name Refined Oil of <i>Nepeta cataria</i> 7% Lotion	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of a Section 3 Me-Too Registration Application

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2, 3 and 6 oz.; bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Vickie Forster	Title Agent for Entomol Products, LLC	Telephone No. (Include Area Code) 302-383-3313
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Vickie Forster</i>	3. Title Agent for Entomol Products, LLC	
4. Typed Name Vickie Forster	5. Date 6 June 2016	

ENTOMOL

GOOD FOR PEOPLE. BAD FOR BUGS.

ACTION: Information and Data Submitted in Accordance with FIFRA Section 3
FEE CATEGORY: B660, 4 month review time. REGISTRATION FEE: \$319.50 total
(includes approved Small Business Waiver of 75% of total PRIA III fee)
E-mail Contact: forsterconsults@gmail.com

CONTAINS CONFIDENTIAL BUSINESS INFORMATION – SUBJECT TO FIFRA SECTION 10(G)

Via Courier

June 6, 2016

Linda Hollis, Branch Chief
U.S. Environmental Protection Agency
Document Processing Desk (BPPD)
Office of Pesticide Programs (REGFEE)
Document Processing Room S-4900 1
Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: ENTOMOL Products, LLC, registration of end-use product substantially similar to
352-902: ENTOMOL 7% Lotion
ENTOMOL Products, LLC Company Number: 91889.

Dear Ms. Hollis:

ENTOMOL Products, LLC is submitting a registration application for an end-use product that is substantially similar to the registered end use product EPA Reg. No. 352-902.

This application includes a transmittal document and three (3) copies of administrative materials and data reports in support of the above-referenced registration action.

ENTOMOL Products, LLC, considers the entire contents of this letter to be subject to protection afforded under FIFRA Section 10(g). Disclosure of this information may be made only in accordance with that Section.

Please call me at 302-383-3313, or contact me via e-mail at forsterconsults@gmail.com if you have any questions regarding this application.

Sincerely,

Vickie Forster

Vickie Forster
Agent for Entomol Products, LLC

Enclosures

cc: Mark Sloneker, Entomol Products, LLC

DATA TRANSMITTAL DOCUMENT

ENTOMOL Products, LLC
Attention: Vickie Forster, Agent for ENTOMOL Products, LLC
Forster & Associates Consulting, LLC
P.O. Box 4097
Greenville, DE 19807

Regulatory Action in Support of Which this Package is Submitted: New me-too end-use product

Information Submitted in Accordance with FIFRA Section 3:

Product Name: ENTOMOL 7% Lotion
EPA Registration No.: 91889-NEW
Transmittal Date: June 6, 2016

Volume Submitted:

Volume No.	Document No.	Guideline No.	Title	MRID
1		N/A	Administrative Materials: Application for Pesticide Registration , EPA Form 8570-1 Confidential Statement of Formula , EPA Form 8570-4 Formulator's Exemption , EPA Form 8570-27 Certification with Respect to Citation of Data , EPA Form 8570-34 Letter of Authorization to Cite Data Data Matrix for ENTOMOL 7% Lotion, EPA Form 8570-35 Product Labeling for ENTOMOL 7% Lotion Small Business PRIA Waiver Request Payment Receipt of PRIA Fee Category B660	

Submitter:

Vickie Forster

Date: 6 June 2016

Vickie Forster
Authorized Agent for ENTOMOL Products, LLC

Company Name: ENTOMOL Products, LLC

Company Contact: Vickie Forster (302-383-3313)
forsterconsults@gmail.com



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Entomol Products, LLC 540 Roosevelt Way San Francisco, CA 94114	EPA File Symbol/Registration Number 91889-NEW
	Product Name Entomol 7% Lotion
	Date of Confidential Statement of Formula (EPA Form 8570-4) 6 June 2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Refined Oil of *Nepeta cataria*

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☒ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Refined Oil of <i>Nepeta cataria</i>	[REDACTED]	[REDACTED]
Signature <i>Vickie Forster</i>	Name and Title Vickie Forster, Agent for Entomol Products, LLC	Date 6 June 2016



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number ENTOMOL Products, LLC, 540 Roosevelt Way, San Francisco, CA 94114; 415-310-2553	EPA Registration Number/File Symbol 91889-NEW
Active Ingredient(s) and/or representative test compound(s) Refined Oil of Nepeta Cataria	Date 6 June 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Outdoor Use	Product Name ENTOMOL 7% Liquid

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☒ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Vickie Forster

Date

6 June 2016

Typed or Printed Name and Title

Vickie A. Forster, Agent for Entomol Products, LLC



United States Environmental Protection Agency
401 M. Street, S.W.
Washington, DC 20460

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DATA MATRIX

Date: 6 June 2016

Applicant's/Registrant's Name & Address:

Entomol Products, LLC
540 Roosevelt Way
San Francisco, CA 94114

EPA Reg. No./File Symbol: 91889-NEW

Product: ENTOMOL 7% Lotion

CAS Registry No. 952722-18-8

OPP Chemical Code 004801

Ingredient: Refined Oil of *Nepeta cataria*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
830.1500 830.1670		CITE-ALL	352	EXC	
830.1700		CITE-ALL	352	EXC	
830.1750		CITE-ALL	352	EXC	
830.1800		CITE-ALL	352	EXC	
830.6302 to 830.7950		CITE-ALL	352	EXC	
870.1100		CITE-ALL	352	EXC	
870.1200		CITE-ALL	352	EXC	
870.1300		CITE-ALL	352	EXC	
870.2400		CITE-ALL	352	EXC	
870.2500		CITE-ALL	352	EXC	
870.2600		CITE-ALL	352	EXC	
870.3100		CITE-ALL	352	EXC	
870.3250		CITE-ALL	352	EXC	
870.5100, 870.5300, 870.5375		CITE-ALL	352	EXC	
870.3700		CITE-ALL	352	EXC	
850.2100		CITE-ALL	352	EXC	
850.2200		CITE-ALL	352	EXC	
850.2200		CITE-ALL	352	EXC	
850.1010		CITE-ALL	352	EXC	
850.1075		CITE-ALL	352	EXC	
850.4400 - 850.4800		CITE-ALL	352	EXC	
880.4350		CITE-ALL	352	EXC	



United States Environmental Protection Agency
401 M. Street, S.W.
Washington, DC 20460

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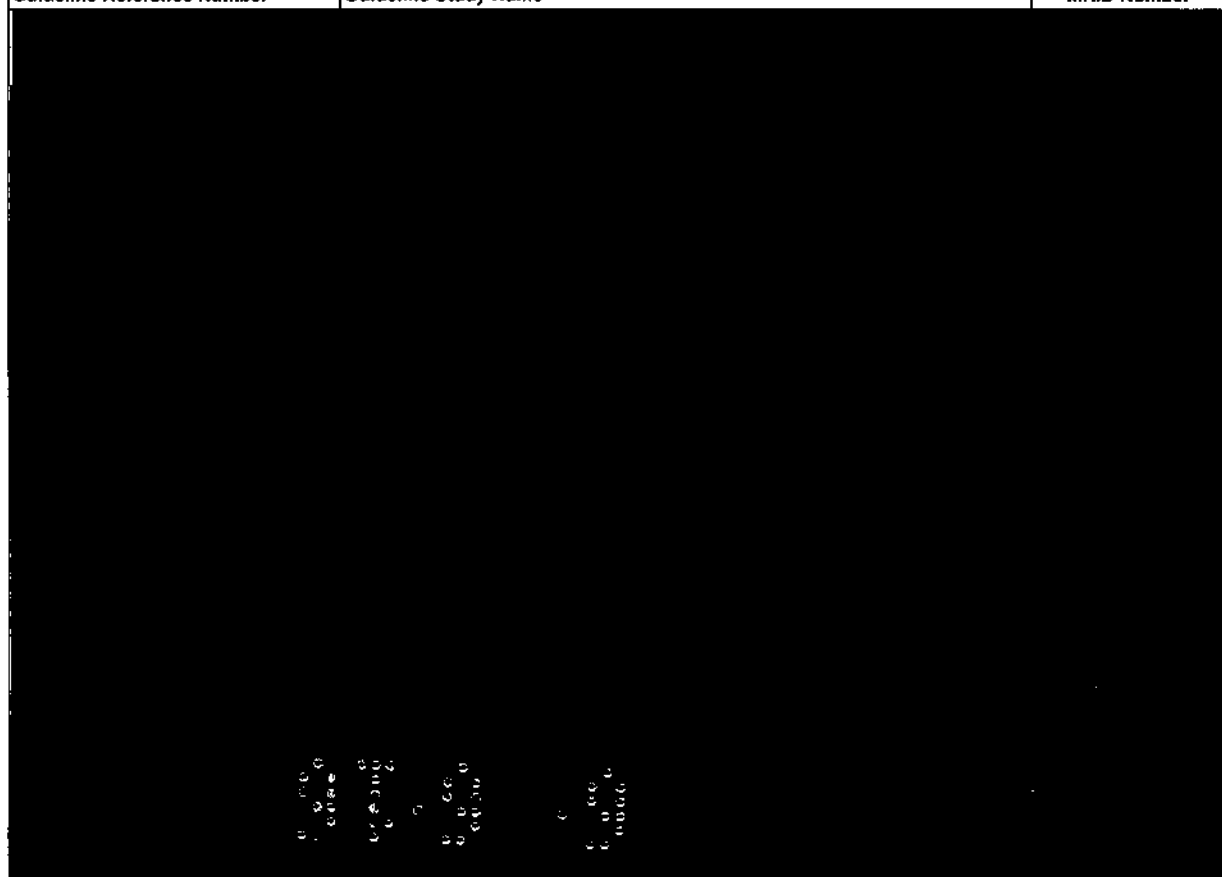
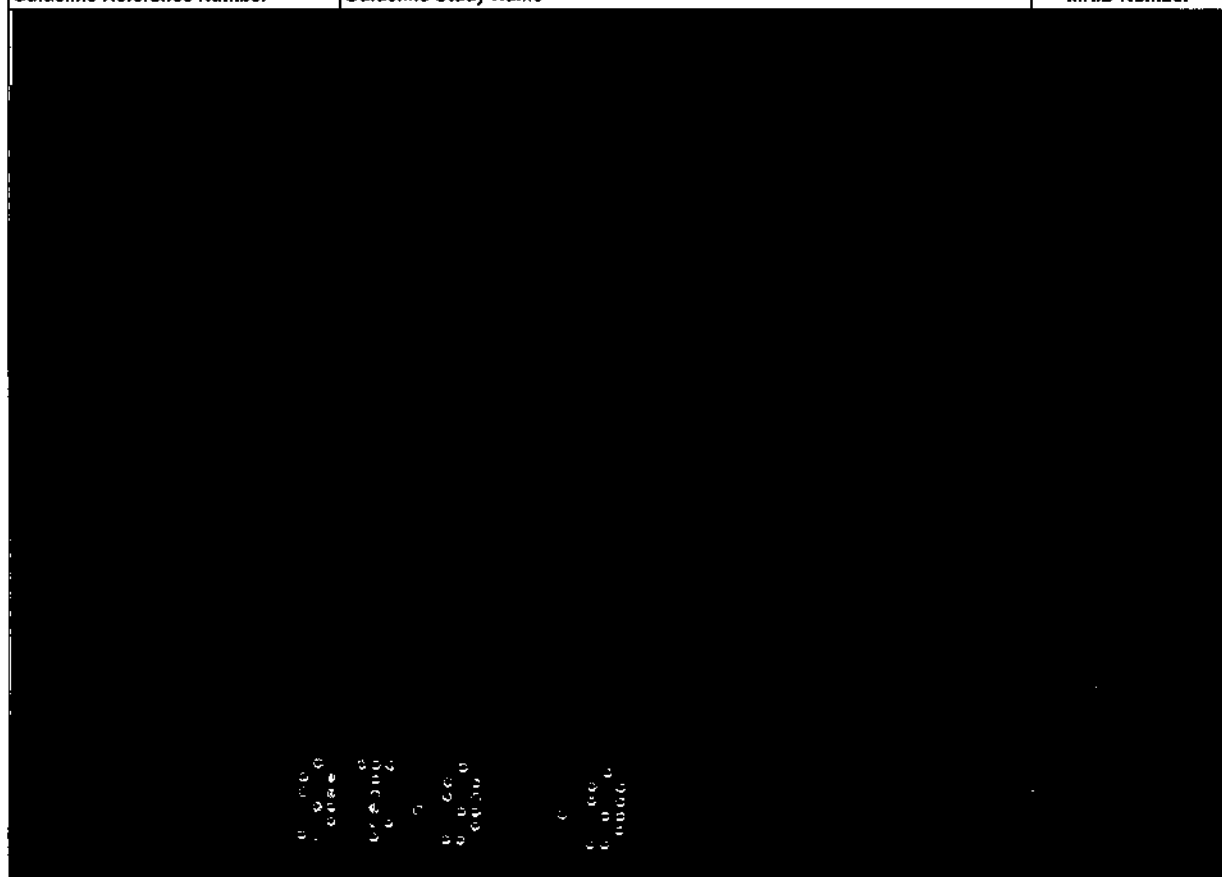
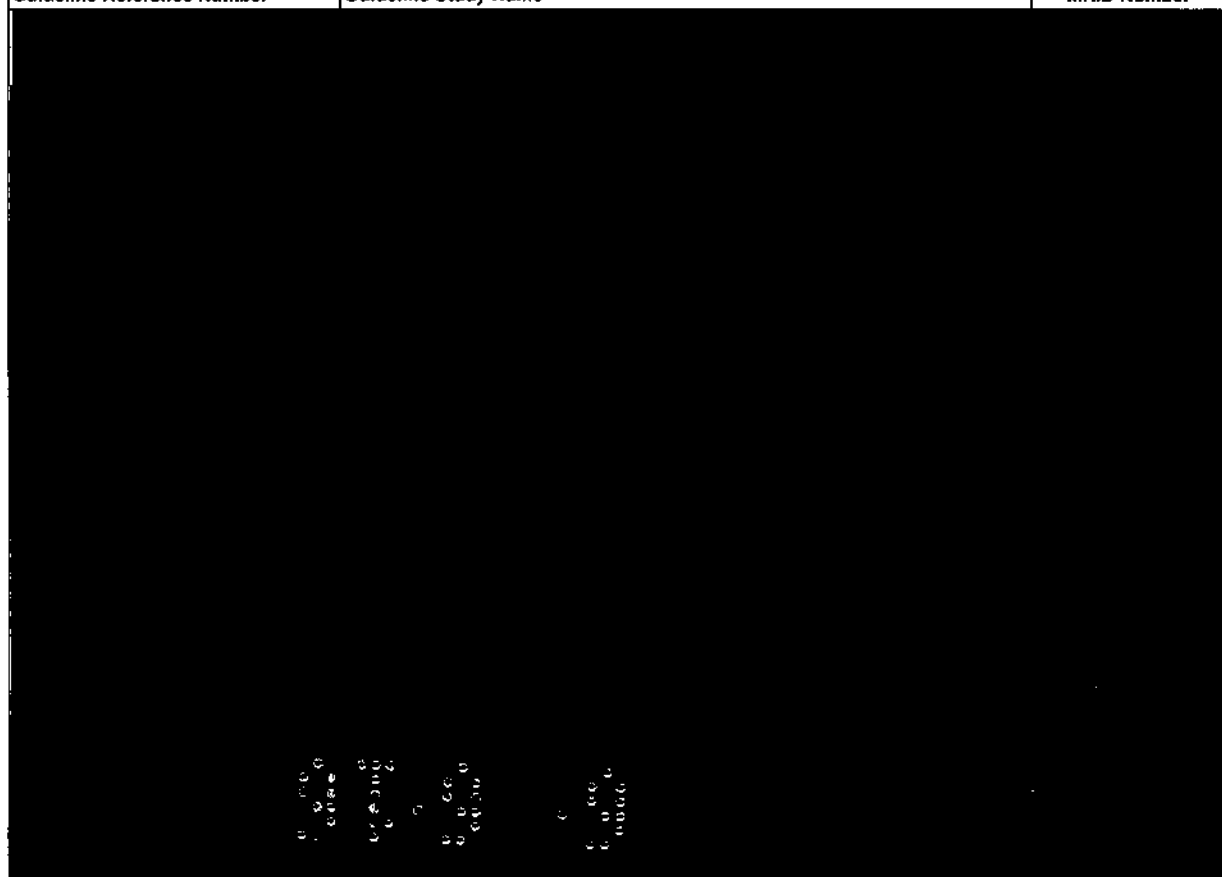
DATA MATRIX

Date: 6 June 2016

Applicant's/Registrant's Name & Address:
Entomol Products, LLC
540 Roosevelt Way
San Francisco, CA 94114

EPA Reg. No./File Symbol: 91889-NEW
Product: ENTOMOL 7% Lotion
CAS Registry No. 952722-18-8
OPP Chemical Code 004801

Ingredient: Refined Oil of *Nepeta cataria*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
			352	EXC	
			352	EXC	
			352	EXC	
			352	EXC	
			352	EXC	
			352	EXC	
			352	EXC	
			352	EXC	
			352	EXC	
			352	EXC	
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			352	EXC	
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			352	EXC	
			352	EXC	
			352	EXC	
			352	EXC	
			352	EXC	
			352	EXC	

Vickie Forster

Signature:
Name and Title: Vickie Forster, Agent for Entomol Products, LLC

Agency Internal Use Copy
Page 1 of 1

125
Date 6 June 2016

() – Denotes optional label language
{ } – Denotes a comment for the reviewer

Refined Oil of *Nepeta cataria* (Entomol 7% Lotion)

(Insect Repellent)(Lotion)
(Skin-applied Lotion to Repel insects)

(ABNs:)

ACTIVE INGREDIENT:

Refined Oil of *Nepeta cataria*..... 7.0%

OTHER INGREDIENTS: 93.0%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See (Back) (or) (Side) (Label Panel(s)) (Product Leaflet) for Additional
Precautionary Statements

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor immediately for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything to an unconscious person.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the poison control center at 1-800-222-1222. For non-emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: www.npic.orst.edu)	

EPA Reg. No. 91889-NEW
EPA Est. No. XXXXX-YY-ZZZ

NET CONTENTS:
BATCH NO.:

Manufactured By:
Entomol Products, LLC
540 Roosevelt Way
San Francisco, CA 94114

() – Denotes optional label language
{ } – Denotes a comment for the reviewer

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS. CAUTION. Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling. If a reaction to this product is suspected, discontinue use and take off contaminated clothing. Discontinue use and consult a doctor if irritation or rash occurs.

PHYSICAL AND CHEMICAL HAZARDS

FLAMMABLE: Keep away from Heat and Open Flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Repellency – Repels biting insects for up to 7 hours.

Do not allow children to handle the product or apply it to themselves. If used on the face, spray/dispense on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face.

Dispense/Spray apply a small amount of liquid directly onto skin. Spread uniformly to completely cover any exposed skin surface. Use sparingly on face and avoid contact with eyes. Reapplication after six hours may be necessary. When applying to children, dispense into an adult's hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin. After returning indoors, wash treated skin with soap and water or bathe. Also wash treated clothing before wearing it again.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Store away from children.

Pesticide Disposal and Container Handling:

Nonrefillable container. Do not reuse or refill this container.

If empty: Place in trash or offer for recycling, if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

() – Denotes optional label language
{ } – Denotes a comment for the reviewer

{NOTE TO REVIEWER: All claims in this section are optional}

- Mosquito repellent
- Blackfly repellent
- Repels mosquitoes
- Repels blackflies
- Effective protection from mosquitoes, biting flies
- Effectively repels mosquitoes and other biting insects
- (Effective) (uncompromised) protection (from a range of biting insects)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis)
- Works great on biting flies
- Protection (from bites) from biting insects (for the whole family).
- Protection for people on the go
- Protection that fits your lifestyle
- Protects from mosquitoes (and) (blackflies) (biting flies) (for up to 7 hours)
- Apply every 6 hours (or as needed)
- Repels insects for up to 7 hours
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours)
- Repels flies (too!)
- Keeps (bugs) (insects) off (your kids) (your family)
- Complete Outdoor protection
- Guards the whole family (safely)
- Protection that fits your (active) lifestyle
- Protect(s) your family at dusk and dawn
- An effective broad-spectrum insect repellent
- Protection during outdoor activities
- (Sport) (Active) (Outdoor) formula
- Safety outdoors for play and on the go
- For yard work and camping
- Protects during work, play or recreation
- Frequent reapplication (and saturation) unnecessary
- Contains (a) plant-based repellent
- Plant based repellent repels (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours)
- Contains plant extracts
- Contains the insect repellent found in (catmint) (catnip) (oil)
- (Plant based) (insect repellent without tradeoffs)
- Always carry (product name)
- For playing and relaxing outdoors
- Not oily, greasy or sticky
- No added fragrance
- Contains no dyes (or added fragrances)
- No chemical odor
- No synthetic odor

() – Denotes optional label language
{ } – Denotes a comment for the reviewer

- No unpleasant odor
 - Leaves pleasant feeling on skin
 - Won't stain
 - (Readily) (Easily) washed off
 - Won't harm plastics
 - Specially formulated to (feel) (and) (smell) better on your skin
 - (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula
 - No residue on skin
 - (It's) Pleasant smelling
 - Feel's comfortable to touch
 - DEET free
 - Non-DEET
 - Non-synthetic
 - Readily washed off
 - New!
 - Sweat Resistant!
-
- Repels (mosquitoes)(,) (blackflies)(,) (biting flies)(,) (and) (biting insects)
 - Repels mosquitoes that may carry (West Nile) (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Cache Valley) encephalitis (for up to 7 hours)
 - Repels mosquitoes that may carry (the) Dengue (virus)
 - Repels mosquitoes that may carry malaria
 - Provides protection from mosquitoes that may carry (the) Dengue (virus)
 - 7 hour insect repellant
 - 7 hour protection
 - (Up to) 7 hours of (effective) mosquito protection
 - (Up to) 7 hours of protection from mosquitoes. Also (protects against) (works on) (repels) (biting flies)(,) (blackflies)(,) (and) (biting insects)
 - Protects for (up to) 7 hours against (mosquitoes)(,) (blackflies)(,) (biting flies)(,) (and) (biting insects)
 - (Protects against) (Fights off) (Repels) (Works on) (mosquitoes)(,) (biting flies)(,) (blackflies)(,) (and) (biting insects)
 - Protects against mosquitoes and (biting flies) (biting insects)
 - Long-lasting protection against (mosquitoes)(,) (blackflies)(,) (biting flies)(,) (and) (biting insects)
 - Effective protection from mosquitoes
 - Effective protection from blackflies
 - Effective protection from biting insects
 - Stay protected for up to 7 hours (from) (mosquitoes)(,) (biting flies)(,) (blackflies)(,) (and) (biting insects)
 - Stay protected for up to 7 hours from mosquitoes that may carry (West Nile) (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Cache Valley) encephalitis
 - Stay protected for up to 7 hours from mosquitoes that may carry (the) Dengue (virus)

() – Denotes optional label language
{ } – Denotes a comment for the reviewer

- Stay protected for up to 7 hours from mosquitoes that may carry malaria
- Proven protection from mosquitoes
- Mosquito protection (for up to 7 hours)
- Biting insect protection that you can feel confident will last up to 7 hours
- Repels mosquitoes (for up to 7 hours)
- Repels blackflies (for up to 7 hours)
- Repels biting flies (for up to 7 hours)
- Easy to (Use) (Apply)
- For (hiking) (fishing) (hunting) (camping) (backpacking)
- Relax and enjoy the (outdoors)(,) (the great outdoors)(,) (backyard)(,) (outside)(,) (park)(,) (woods/forest) with up to 7 hours of protection against (mosquitoes) (biting flies) (blackflies) (biting insects)
- Portable protection
- Comfortable feel with no chemical (odor)(smell)
- Comfortable feel with pleasant smell
- Long-lasting
- Contains Refined Oil of *Nepeta cataria*

New Marketing statements:

- Essential oil based repellent, not a synthetic chemical.
- Plant based essential oil insect repellent.
- Essential oil insect repellent with 7 hours of effective protection [against] [mosquitoes] [and] [biting insects]
- EPA registered essential oil insect repellent with 7 hours of effective protection [against mosquitoes] [and biting insects]
- An essential oil repellent that repels biting insects that may transmit insect borne diseases.
- An essential oil repellent that protects against insects that carry Dengue, Malaria, West Nile and other insect borne diseases.
- Repels mosquitoes that may carry Dengue, Malaria, West Nile Virus, Encephalitis, Chikungunya Virus and Zika Virus.
- Effective mosquito repellent
- Repels mosquitoes for 7 hours, which may carry Zika Virus, West Nile Virus, Malaria, Dengue, Encephalitis and Chikungunya Virus.
- Repels mosquitoes that may carry the Zika Virus for 7 hours.
- An essential oil repellent with 7 hours of efficacy that can be used on infants, and re-applied without worry.
- The only plant based, essential oil product that protects against insect borne diseases for up to 7 hrs.
- Plant based, essential oil that repels insects for 7 hours that may carry insect borne disease
- A plant based insect repellent with 7 hours of effective protection
- Good for people, bad for bugs
- Protects people, repels bugs
- Produced from a renewable resource

INERT CLEARANCE STATUS FORM

Reviewer Name: Marc Sheahin			Request Date: 6/15/2016
Tel: 703-347-8686	ISB	CUBE: S-4811	MAIL CODE: 7502P

A. COMMENTS:

Inert Issue: The inert ingredients are not found in the Agency database.

B. PESTICIDE PRODUCT INFORMATION:

Receipt Number: 987299	Date on CSF: 06/06/2016	Food-Use Pesticide: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
EPA Reg. No/File Symbol: 91889-E	Formulation: Basic	

C. INGREDIENT INFORMATION:

Ingredient No.1	Tolerance Exemption(s) ¹					
	910	920	930	940	950	960
Chem. Name:	OK now					
Trade Name:						
CAS Reg. No:						
Comments: The inert is not found in the Agency database. ✓						

Ingredient No. 2						
Chem. Name:	OK					
Trade Name:						
CAS Reg. No:						
Comments: The inert is not found in the Agency database.						

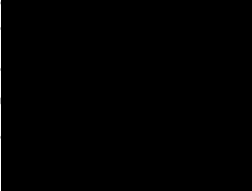
Reviewer Name: Marc Sheahin

Review Date: 06/15/2016

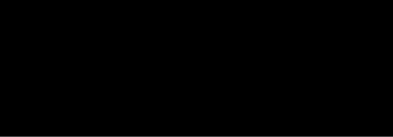
¹Language from the Code of Federal Regulations (40 CFR 180, subpart D):

40 CFR 180.910: Inert ingredients used pre- and post-harvest; 40 CFR 180.920: Inert ingredients used pre-harvest; 40 CFR 180.930: Inert ingredients applied to animals; 40 CFR 180.940: Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations; 40 CFR 180.950: Tolerance exemptions for minimal risk active and inert ingredients; and 40 CFR 180.960: Polymers.

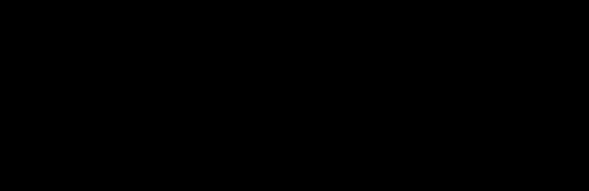
Ingredient No. 3

Chem. Name		<i>OK</i>							
Trade Name									
CAS Reg.									
Comments: The inert is not found in the Agency database.									

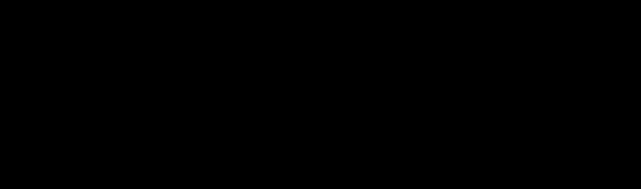
Ingredient No. 4

Chem. Name		<i>OK</i>							
Trade Name									
CAS Reg.									
Comments: The inert is not found in the Agency database.									

Ingredient No. 5

Chem. Name									
Trade Name									
CAS Reg.									
Comments: The inert is not found in the Agency database.									

Ingredient No. 6

Chem. Name		<i>nm</i>							
Trade Name									
CAS Reg.									
Comments: The inert is not found in the Agency database.									

